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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,386	04/19/2006	Girij Pal Singh	SMC-PT009	3611
3624	7590	12/03/2007	EXAMINER	
VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103			LOEWE, SUN JAE Y	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			12/03/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/576,386	<b>Applicant(s)</b> SINGH ET AL.	
	<b>Examiner</b> Sun Jae Y. Loewe	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                  |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                             | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4-19-2006</u> | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

1. Claims 1-3 are pending in the instant application.

#### *Information Disclosure Statement*

2. The information disclosure statement (IDS) submitted on April 19, 2006 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS was considered. A signed copy of form 1449 is enclosed herewith.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3 rejected under 35 U.S.C. 112, first paragraph. The specification is enabling for a process for preparing the claimed crystalline form of perindopril erbumine using the following solvents: ~~N,N-dimethylformamide~~, dimethoxymethane, 2,2-dimethoxypropane, 1,2-dimethoxyethane. The specification does not reasonably provide enablement for the full scope of solvents claimed:

“ dimethyl acetals of lower aliphatic aldehydes, dimethyl ketals of lower aliphatic ketones and 1, 2- dimethoxyethane ”

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737,

8USPQ2s 1400, 1404 (Fed. Cir. 1988). MPEP 2164.01(a) states “There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue”. The factors are applied below to the instant claims.

*The breadth of the claims*

The claims are drawn to process of making crystalline form of perindopril erbumine identified by the x-ray diffraction pattern recited.

*The nature of the invention*

The solvents usable for the process are broadly claimed: **dimethyl acetals of lower aliphatic aldehydes, dimethyl ketals of lower aliphatic ketones and 1,2-**. Furthermore, the term “lower aliphatic” is not defined in the specification. Thus, within the broadest reasonable interpretation, all acetals, ketals and dialkoxyethane included within the claimed scope.

*The state of the prior art/level of ordinary skill/level of predictability*

The level of predictability in the art for preparing specific solid forms is low. Guillory describes various methods for obtaining unique solid forms (p. 183 – p. 184). The preparation of solid forms is variable and extremely sensitive to the procedure employed. Thus, different solid forms of a single compound may arise as a result of altering experimental procedures. Guillory states (p. 193):

“Among the factors affecting the types of crystals formed are (a) the solvent composition or polarity, (b) the concentration or degree of supersaturation, (c) the temperature, including cooling rate and the cooling profile, (d) additives, (e) the presence of seeds, (f) pH, especially for salt crystallization, and (g) agitation.”

*The amount of direction provided by the inventor/existence of working examples*

Direction/working examples limited to processes performed using the following: **N,N-dimethylformamide**, one type of acetal (dimethoxymethane), one type of ketal (2,2-dimethoxypropane), one type of dialkoxyethane (1,2-dimethoxyethane).

*The quantity of experimentation needed to make or use the invention*

The state of the art precludes one of ordinary skill predict/determine a particular solid form based on procedural limitations such as solvent system used. Thus, the preparation of a particular solid form using one solvent of a genus does not enable one of ordinary skill to prepare the same solid form using all solvents of a genus. Thus, one of ordinary skill is not enabled by the instant disclosure to practice the invention commensurate in scope with the claims. The amount of experimentation is undue.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites the term "selective". This term is not defined in the instant specification. The art recognized definition is "highly specific in activity or effect" (<http://www.m-w.com/dictionary>). Lacking a specific definition in the disclosure, it is unclear what Applicant intends to claim. For example, "selective" could be interpreted as a further limitation that narrows the scope of the process recited on p. 12. Because a meaning could not be ascertained for the term "selective", it was not examined herein.

Appropriate clarification/correction is requested. Alternatively, deletion of the term "selective" overcomes this ground of rejection.

5. Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites the term "gradually". A specific definition is not provided in the instant specification, therefore the art recognized definition is noted herein.

"taking place, changing, moving, etc., by small degrees or little by little." (<http://dictionary.reference.com/browse/gradually>)

Thus, the term “gradually” is a relative term that requires a specific standard of measuring the degree intended (MPEP § 2173.05(b).F). Absent such standard, the term renders the claim indefinite. The claim limitation “gradually” was not examined herein.

Appropriate clarification/correction is requested. Alternatively, deletion of the term “gradually” overcomes this ground of rejection.

6. Claim 2 recites the limitation "...~~acetals~~ of lower aliphatic aldehydes and ketones". There is insufficient antecedent basis for the limitation "...acetals ... of lower aliphatic ketones" in the claim. The parent claim 1 is drawn to "...ketals of lower aliphatic ketones". Appropriate correction is requested.

*Allowable Subject Matter*

7. The claimed process is not anticipated nor made obvious by the prior art. The art teaches/suggests processes of making crystalline forms of perindopril erbumine using solvents that are different from the ones instantly claimed. For example: ethyl acetate (eg. Baliarda et al.), dichloromethane (eg. WO01/87836), chloroform (WO01/83439), acetonitrile (Dubuffet et al.). See also instant specification p. 17-19.

*Conclusion*

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

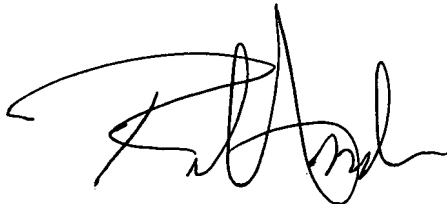
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sun Jae Y. Loewe  
Art Unit 1626

A handwritten signature in black ink, appearing to read 'Rebecca Anderson', with a large, sweeping initial 'R' and 'A'.

REBECCA ANDERSON  
PRIMARY EXAMINER